

REMARKS

I. Applicants' Invention and Preliminary Comments.

Applicants, through the undersigned attorney wish to thank the Examiner for the courtesy extended during the personal interview conducted on May 12, 2004. During that Interview the definition of "resistant starch" was discussed as were amendments to the claims to distinguish over the prior art. As such the Examiner's Interview Summary is accurate.

The claims have been amended to recite that the method comprises the step wherein at least 10% of the individual's daily carbohydrate intake is replaced with resistant starch and the claims which previously recited the language of non-elected claim 13 have been further amended to recite that this resistant starch amount is at least 10 grams and comprises at least 10% of the total starch content. These amendments are supported in the description provided in the specification including at pages 9 and 15 wherein preferred amounts and proportions of resistant starches are discussed. Moreover, these amounts correspond to Applicants' Example 4 wherein the experimental diet of the invention provided 9.4 grams per day of resistant starch and that resistant starch accounted for 16.5% of the individual's daily carbohydrate intake. (See also the Rule 132 Declaration of Ian Brown submitted on October 12, 2003.)

The results from Example 4 illustrate Applicants' discovery that 1) replacing at least 10% of an individual's daily carbohydrate intake with resistant starch, and 2) at least 10% of the individual's saturated fat intake with unsaturated fat provides numerous improvements to carbohydrate and lipid metabolism including: a) enhancing carbohydrate and fat metabolism, b) reducing plasma leptin concentrations, c) increasing satiety, d) lowering the risk of obesity, e) lowering the risk of non-insulin dependent diabetes mellitus, f) lowering post-prandial glucose and/or insulin levels, and g) helping control an individual's body mass.

II. Outstanding Rejections

Claims 1-5, 7-10, 26-28 and 30-33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Laughlin et al., U.S. Patent No. 5,470,839.

Claims 1-10 and 26-33 stand rejected over Laughlin in view of Watanabe, U.S. Patent 5,300,311 and Garg, American Journal of Clinical Nutrition, 1998.

III. Patentability Arguments

A. Applicants' Claims are Clear that "Resistant Starch" When Recited in Conjunction with Weights and Percentages in the Claims Refers to that Portion of Starch Which Acts Like Dietary Fiber and is Not Absorbed in the Small Intestine of Healthy Individuals.

In response to the point raised by the Examiner during the Interview, Applicants confirm that the term "resistant starch" as used in their claims refers to that portion of starch which acts like dietary fiber and is resistant to digestion. Moreover, Applicants submit that the recitation of "resistant starch" in conjunction with percentages (e.g., 10% resistant starch) or weights (e.g., 2 grams resistant starch) in the claims would be understood to refer to the portion of starch in starch or other products which is itself resistant to digestion and would not be ambiguous to those of ordinary skill in the art upon reading Applicants' specification. (See the accompanying Declaration of Ian L. Brown Ph.D. which states that "the use of the term 'resistant starch' in conjunction with a percentage or weight would invariably be understood by those of skill in the art to refer to the resistant starch portion of that starch." (emphasis in the original))

Resistant starch is starch which when consumed resists enzymatic digestion and acts like dietary fiber. Brown et al., Food Australia 47: 272-275 (1995) referred to at page 5, lines 20 and 21 in Applicants' specification notes that European Food-Linked Agro-Industrial

Research - Concerted Action on Resistant Starch 1991 (EURESTA) defined resistant starch as "the sum of starch and products of starch not absorbed in the small intestine of healthy individuals." (Brown et al., p. 272 Resistant starch exists in several types RS1 (physically inaccessible starch), RS2 (resistant starch granules such as present in high amylose starch), RS3 (retrograded starch, such as heat and moisture treated), and RS4 (chemically modified starch, such as starch esters and ethers and crosslinked starches).

As noted in the specification and in prior art literature resistant starch is present in various proportions in different natural and processed starches. Such starches are referred to as having a resistant starch content by which is meant that proportion of the product or starch which is resistant starch. Thus, the specification at page 3, lines 18-22 refers to "constituents with a low resistant starch content" and with "a high resistant starch content." Further, the specification teaches at page 6, lines 12-13 that "[s]tarches can also be treated to enhance the resistant starch content by a number of physical or chemical means." Applicants also refer to the disclosure of McNaught et al. WO 94/14342 (pg. 4, Table 1) in which the resistant starch levels of various maize starches from waxy maize to high amylose starch are analyzed. (As discussed later, this reference teaches that waxy maize starch has a low resistant starch content while high amylose starches tend to have higher resistant starch contents increasing with higher amylose levels.) Further, Example 4 of Applicants' specification refers to the resistant starch content of both "traditional" starches and Hi-maize™ high amylose starches (See page 25, line 21). The claims of the present application also distinguish between resistant starch and starch which comprises a resistant starch component. (see claim 13 which specifies that "resistant starch is present in a proportion of at least 5% by weight of the total starch content.")

While starches such as high amylose starch might occasionally be informally referred to as "resistant starch" the use of the term "resistant starch" in conjunction with a percentage or weight would invariably be understood by those of skill in the art to refer to the resistant starch portion of that starch. Hence the reference to resistant starch content in the specification at page 3 as well as the discussion in the application Examples makes clear that quantitative references to "resistant starch" are to the resistant starch portions of starches and food products comprising resistant starch. Thus, while the application examples and disclosures such as McNaught WO 94/14342 make clear that even traditional starches and starch containing food products have a resistant starch content they are not resistant starch. Similarly, products comprising high amylose maize starch have a resistant starch content and are not "resistant starch."

For these reasons, Applicants' recitation of "resistant starch" in conjunction with percentages or weights in the claims would be understood to refer to the portion of starch in starch or other products which is itself resistant to digestion and would not be ambiguous to those of ordinary skill in the art.

**B. The Rejection Under 35 U.S.C. §102(b)
over Laughlin et al. Should be Withdrawn.**

The anticipation rejection over Laughlin U.S. Patent No. 5,470,839 should be withdrawn because Laughlin fails to disclose replacement of "at least 10% of an individual's daily carbohydrate intake with resistant starch." While Laughlin teaches the incorporation of high amylose starch of unspecified amylose content as one carbohydrate component of its dietary formulation it should be noted that only a small fraction of high amylose starch is resistant starch. As discussed in the accompanying Declaration of Ian Brown, Ph.D. the ~~†~~ resistant starch content of high amylose starch varies in the range of from 7.5% (High

Amylose 50) to as high as 22% (High Amylose 80). When this is combined with the recognition that Laughlin discloses a high amylose content of 23% of carbohydrate content Laughlin fails to disclose a diet in which resistant starch would exceed 5% (i.e., $23\% \times 22\% = 5\%$).

Moreover, under the principles of "inherent anticipation" there is no circumstance in which the Laughlin formulations would invariably result in the administration of resistant starch in a proportion of at least 10% of total starch or carbohydrate content. This is the case because Laughlin neither specifies the particular high amylose starch being used nor instructs one to use a quantity of high amylose starch that would invariably result in the administration of 10 grams of resistant starch. With this being the case, the anticipation rejection under 35 U.S.C. §102 over Laughlin should be withdrawn.

C. The Rejection Under 35 U.S.C. §103(a) over Laughlin et al. in View of Watanabe and Garg Should be Withdrawn.

The obviousness rejection over Laughlin in combination with Watanabe and Garg should also be withdrawn because there is no teaching in Laughlin that would motivate one to replace at least 10% of an individual's carbohydrate intake with resistant starch much less to do so in combination with replacing at least 10% of the individual's saturated fat intake with unsaturated fat. Moreover, there is nothing in either Watanabe or Garg which would so motivate one to alter the disclosure of Laughlin.

Laughlin fails to disclose a diet replacing at least 10% of an individual's carbohydrate intake with resistant starch. In fact, when it discloses using 23g of high amylose starch (see the first Example Table) it can provide no more than 5 grams of resistant starch and then only when the high amylose starch is 80% amylose which has a maximum of 22% resistant starch. (Laughlin et al. only teach 25% to 75% high amylose which have lesser resistant starch

contents.) Moreover, Laughlin fails to suggest levels of resistant starch higher than 5% in its formulations. While, Laughlin discloses using high amylose starch it does not teach doing so at a level that would result in replacing at least 10% of an individual's carbohydrate intake with resistant starch. While Laughlin acknowledges that high amylose starch contains resistant starch it does not address the issue of the variability in the proportions of high amylose starch that is resistant. Without such discussion, it is clear that Laughlin is not concerned with the proportions of starch which are resistant. Thus, Laughlin fails to recognize the importance of the resistant starch content of the high amylose starch and the advantages provided by using resistant starch according to Applicants' invention.

Neither Watanabe nor Garg, make up for the deficiencies of Laughlin with respect to independent claim 1 of the applications. Watanabe is directed to a method of modifying wheat flour as an alternative to high amylose maize (amylomaze starch) because of problems with regard to its taste and texture. (see col. 1, lines 49-56) In this manner, Watanabe teaches away from elevating the content of high amylose maize in compositions such as Laughlin's and would not lead one to modify Laughlin to arrive at the claimed invention.

Garg also fails to make up for the deficiencies of Laughlin in making the claimed invention obvious. Garg provides a contrasting comparison between a high-carbohydrate diet and a monounsaturated diet. Garg finds that compared with high-carbohydrate diets, high monounsaturated fat diets improve lipoprotein profiles as well as the glycemic profile (see page 581, col. 2, lines 26-28) and concludes that a diet rich in cis-monounsaturated fats may be advantageous for improving lipoprotein and glycemic profiles in patients with diabetes mellitus (see page 581, col. 2, lines 45-47). Garg does not disclose or suggest a diet comprising resistant starch and does not suggest that a diet high in monounsaturated fats

should be combined with any other diet. For this reason, Garg fails to make up for the deficiencies of Laughlin with respect to independent claim 1.

In addition, the obviousness rejections of claims 6 and 29 directed to treating individuals suffering from obesity should be withdrawn because Noakes et al., *The American Journal of Clinical Nutrition*, Vol. 64, pages 944-951 (1996) discussed in the previous Office Action and the response filed October 17, 2003 teaches away from replacing carbohydrates with resistant starch in diets for hypertriglyceridemic subjects who are overweight. As discussed previously, Noakes et al. teach that replacing carbohydrates with resistant starch in a diet: 1) showed no benefit in insulin sensitivity or plasma lipid responses, 2) caused dyslipidemia to worsen, and 3) accentuated the risk of coronary artery disease. This teaches away from Applicants' discovery that replacing carbohydrates and lowering fats in a diet has the benefits of a) reducing plasma leptin concentrations, b) lowering the incidence or risk of non-insulin dependent diabetes mellitus, and c) reducing post-prandial glucose and/or insulin levels.

Specifically, Noakes et al. teach that replacing as much as 25% of an overweight hyperglyceridemic subject's daily carbohydrate intake with resistant starch does not have a positive metabolic effect on plasma lipids and that replacing as much as 33% had only a small reduction in plasma insulin concentrations. (See page 8, third paragraph). In addition, Noakes et al. suggest that such replacements in combination with changes in fat intake can cause dyslipidemia to worsen. Specifically, Noakes et al. teach that:

"other studies that have made similar dietary changes in carbohydrate and fat (8,9) or fibre separately have not shown any benefit in insulin sensitivity or plasma lipid responses and in fact, dyslipidemia has been shown to worsen."
(See Abstract, Lines 15-18).

Accordingly, the cited references fail to teach that replacing as little as 5% of an individual's daily carbohydrate with resistant starch in combination with replacing at least 10% of an individual's saturated fat intake with unsaturated fat would be successful in achieving the health benefits recited in the claims of the present invention. Accordingly, the rejections over Laughlin et al., either alone or in combination with Watanabe and Garg should be withdrawn and each of claims 1-10 and 26-33 should be allowed.

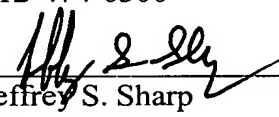
CONCLUSION

For all of the foregoing reasons, the rejection should now be withdrawn and an early notice of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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June 7, 2004

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